

SUMMARY OF STERILE COMPOUNDING INSPECTION

Pharmacy _____ Permit _____ Date _____

AREA	COMPLIANT	PARTIALLY COMPLIANT	NONCOMPLIANT	NA
Policies and Procedures				
Training				
• Initial - All Compounding Personnel				
• Ongoing - All Compounding Personnel				
• Training Non Pharmacy Personnel				
• Written Exams				
• Hand Hygiene & Garbing Observed				
• Cleaning PEC & Rooms Observed				
• Media Fill				
• Gloved Fingertip Testing				
Garbing				
Compound Area Environment				
• Physical				
• Accessories				
• HEPA Filters				
• Pressures				
• Temperatures				
Cleaning Compound Area Daily				
• Ante Room				
• Buffer Room				
• Primary Engineering Control				
• Equipment				
Cleaning Compound Area Monthly				
• Ante Room				
• Buffer Room				
• Equipment				
Certification of Compound Area				
• ISO Classifications				
• Air Changes Per Hour				
• Smoke Test				
• Pressure Differential				
• Particle Counts				
Environmental Monitoring				
• Viable Air Sampling				
• Surface Sampling				
Compounding Procedures				
• Prohibited Objects Not in Areas				
• Sterile 70% IPA Used Appropriately				
• Sterile Gloves Used Appropriately				
• Aseptic Technique				
• Single & Multiple Dose Vials				
• Compound Record				
• Pharmacist Checks				
• Labels				
• Beyond Use Dating				
Continuous Quality Improvement				
High Risk				
• Active Pharmaceutical Ingredients				
• Sterilization				
• Depyrogenation				
Extending Beyond Use Dates/ Testing Required				
• Sterility Testing				
• Endotoxin Testing High Risk				
• Stability Data				
Transporting Outside Facility				
TOTALS				